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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/671,967 | 09/25/2003 | Jeffrey O. Saunders | VPI/98103DIV | 7271 |

1473 7590 05/23/2007
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
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NEW YORK, NY 10036-8704

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| EXAMINER |
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KUMAR, SHAILENDRA

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| ART UNIT | PAPER NUMBER |
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1621

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| MAIL DATE | DELIVERY MODE |
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05/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/671,967 | Applicant(s) SAUNDERS ET AL. | |
| | Examiner SHAILENDRA -. KUMAR | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-40 is/are pending in the application.
- 4a) Of the above claim(s) 21-35 and 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-20 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/07 has been entered.

Claims 19-40 are pending in this application. Claims 21-35 and 37-40 are withdrawn from the consideration, being drawn to the non-elected invention.

Claim Rejections - 35 USC § 102

2. Claims 19-20 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishino et al(US 6,071,968).

Nishino et al, various claims, column 7, line 67 and column 8, line 34 and 35-36 anticipate instant claimed composition in terms of oral and inject able composition. Use of two or more compositions are well known in the pharmaceutical art. Note when R2 and R3 are H, R1 is alkyl, it reads on the instant claims when in the instant claims, X is CONH, one of R7-&11 is NH2, and one of R1 to R5 is OH and other two are alkyl.

Claim Rejections - 35 USC § 103

3. Claims 19-20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishino et al.

Nishino et al teach structurally similar compounds and composition as claimed in herein for use as pharmaceutical composition by administering orally or by injection, see various claims, column 7, line 67, column 8, line 34 and 35-36. The difference between the reference and herein claimed composition is that the reference has not made exact compositions and have not made composition using two or more compositions.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds and composition within the generic disclosure of the reference because they are structurally so similar to those claimed herein, with the reasonable expectation of achieving successful oral and injectable composition, absent evidence to the contrary. It is obvious to combine tow compositions. In re Kerkoven 205 USPQ 1069.

Double Patenting

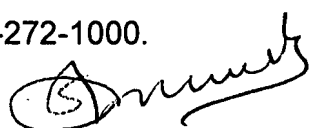
4. Claims 19-20 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,653,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the definition of X in the instant claims overlaps the corresponding definition in the patent. Also it is well known to add additional ingredient to any composition to treat a disease.

Art Unit: 1621

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
5/21/07